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VB

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/084,491	05/27/98	MOORE	11375

022195  
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HM12/1124

EXAMINER  
SLOBODYANSKY, E

ART UNIT	PAPER NUMBER
1652	

DATE MAILED:

11/24/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

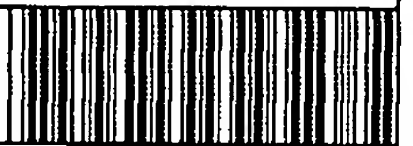
# Office Action Summary

Application No.  
**09/084,491**

Applicant(s)  
**Moore et al.**

Examiner  
**Elizabeth Slobodyansky**

Group Art Unit  
**1652**



☒ Responsive to communication(s) filed on Oct 14, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 21-75 is/are pending in the application.

Of the above, claim(s) 55 and 56 is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 21-54 and 57-75 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5, 10, 12

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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### **DETAILED ACTION**

The amendment filed October 14, 1999 (Paper No. 11) amending the specification to correct typographical errors, canceling claims 1-16, 18 and 20 and adding claims 21-75 has been entered.

### ***Election/Restriction***

Applicant's election with traverse of Group I in Paper No. 11 is acknowledged. The traversal is on the ground(s) that the searches for Groups I-III would be overlapping (page 12, 1st paragraph). This is not found persuasive because while the searches for Groups I-III are overlapping, they include searches of additional classes/subclasses for each Group. For example, the search for Group III would include search of class 530, subclasses 387.1 that is not required for Groups I and II.

The requirement is still deemed proper and is therefore made FINAL.

Claims 17 and 19 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected inventions, the requirement having been traversed in Paper No. 11.

Newly submitted claims 55 and 56 are directed to an invention that is independent or distinct from the invention originally elected for the following reasons: a composition comprising a DNA implies gene therapy as an intended use (page 5, lines 9-15). Methods of gene therapy require divergent considerations and a search of

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additional classes/subclasses such as 424/93.1 and 514/44 in addition to classes/subclasses 435/212, 252.3, 320.1 and 536/23.2, 24.31 required for the search of Group I.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 55 and 56 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 21-54 and 57-75 are under consideration.

***Information Disclosure Statement***

The information disclosure statement filed October 28, 1999 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered.

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Applicant indicates that "the relevance of Japanese language document can be found in the drawings". Such explanation is insufficient because the legends to the drawings are given in Japanese.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21, 46, 47, 57 and 75 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 21, 46, 47, 57 and 75 recite ATCC Deposit No. 209023. The deposit was made under the terms of the Budapest Treaty on May 5, 1997 (page 7, lines 22-26). However it is not apparent whether the deposit is readily available to the public. An affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney or record over his/her signature, and registration number, stating that the specific strain(s) has/have been deposited under the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably

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removed upon the granting of a patent, would satisfy the deposit requirements. See 37 C.F.R. § 1.808.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 72-75 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well established utility.

Claims 72-75 are drawn to a nucleic acid molecule comprising 30- and 50 nucleotide fragments of SEQ ID NO:1 (claims 73 and 74) or comprising fragments that are 95% identical to fragments of SEQ ID NO:1 (claims 72 and 75). "A nucleic acid molecule" of claims 72-75 is not limited in length to said fragments. Therefore, claims 72-75 encompass countless number of sequences with an unknown function. There is no guidance presented as to what is the specific function of the sequences. With regard to claims 72 and 75, there is no guidance as to which amino acid residues are important in the function of t-PALP and therefore, what are the residues that can be substituted, deleted or added without affecting the function. Although it is routine in the art to make polypeptides based on a nucleotide or amino acid sequence, it is not routine and it is extremely unpredictable what the structure of this particular polypeptide

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would be and how this polypeptide, once made, could function. Due to the unpredictable nature of the art, the lack of guidance set forth by the specification regarding a specific function of a protein, and a great number of encompassed polypeptides, it would require undue experimentation for one skilled in the art to find the use for a peptide encoded by a nucleic acid molecule of claims 72-75.

Claims 72-75 also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 69 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

While applicant may be his or her own lexicographer, a term in a claim may not be given a meaning repugnant to the usual meaning of that term. See *In re Hill*, 161 F.2d 367, 73 USPQ 482 (CCPA 1947). Claim 69 is drawn to a method for producing a protein wherein the protein has amino acid sequence of residues 4 to 63 of SEQ ID

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NO: 2. According to the US Patent Classification System (class 530/350), the term "protein" encompasses more than 100 amino acid residues.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 21, with dependent claims 22-54, and claim 57, with dependent claims 58-71, are rejected under 35 U.S.C. 102(a) as being anticipated by Du et al., Hudson (a), Hudson (b) or Adams.

Du et al. (accession AC002073, May 12, 1997), Hudson (a) (accession G24591, May 31, 1996), Hudson (b) (accession G24430, May 31, 1996), and Adams (accession G20845, July 24, 1996), all references cited on form PTO-1449 filed March 8, 1999, teach sequences comprising fragments of a nucleic acid sequence complementary to fragments of SEQ ID NO:1. Since claims 21(e) and 57(e) are not limited to a full-length sequences, any of the Du et al., Hudson (a), Hudson (b) or Adams sequences anticipate a nucleic acid molecule recited in claims 21(e) and 57(e).



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Claims 21, with dependent claims 22-54, and claim 57, with dependent claims 58-71, are rejected under 35 U.S.C. 102(b) as being anticipated by Hillier et al.(a), or Hillier et al.(b).

Hillier et al.(a) (accession N29083, January 4, 1996) and Hillier et al.(b) (accession N56924, February 22, 1996), references AG and AH, respectively, cited on form PTO-1449 filed October 14, 1999, teach sequences comprising fragments of a nucleic acid sequence complementary to fragments of SEQ ID NO:1. Since claims 21(e) and 57(e) are not limited to a full-length sequences, any of the Hillier et al. (a) or Hillier et al (b) sequences anticipate a nucleic acid molecule recited in claims 21(e) and 57(e).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky whose telephone number is (703) 306-3222. The examiner can normally be reached Monday through Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX phone number for Technology Center 1600 is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Center receptionist whose telephone number is (703) 308-0196.



Elizabeth Slobodyansky, PhD  
Patent Examiner